UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT, **CASE NO.: 08-cv-358-JL**

Plaintiff,

Judge Joseph N. Laplante

vs.

MUTUAL PHARMACUETICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC.,

Defendants.

PLAINTIFF'S MOTION TO EXCLUDE OR LIMIT EXPERT TESTIMONY

RELIEF SOUGHT AND BASES FOR SAME

Plaintiff respectfully seeks to exclude or limit the following opinions or testimony:

1. that no expert be permitted to opine contrary to the law enunciated by this Court, *Bartlett v. Mutual Pharmaceutical Company, Inc*., 659 F.Supp.2d 279 (DNH 2009);

2. that no expert be permitted to opine contrary to the law enunciated by apparently every post *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), opinion;

3. that no expert be permitted to opine that a "non-RLD" (not the reference listed drug) generic drug manufacturer could not submit a changes being effected unilateral label change to enhance, strengthen or modify safety or risk information in their label or package insert;

4. that Dr. Ehrreich not be permitted to opine as he did in his report to the effect that

   a. "[i]t is disingenuous to argue that ANDA holders can make changes to a generic drug label that would make it different from the RLD" (Ex. 1 at 4),
   b. "[i]t would be inconsistent with industry practice and a violation of FDA policies and procedures for an ANDA holder to submit a certification of sameness while, at the same time, submitting a label that is different" (Ex. 1 at 4),
   c. "[g]eneric firms are not permitted by FDA to take unilateral actions of any kind while there product is on the market without FDA approval" (Ex. 1 at 18), and
   d. "it is my opinion today that only the FDA in concert with the Review Division who approved the original NDA (RLD) may alter the labeling", (Ex. 1 at 13),

   for reasons including that his first three quoted opinions would be opining that this Court's opinions and the opinions of the Fourth, Fifth and Eighth Circuit Courts of

Appeals are disingenuous and wrong, respectively[1], and the fourth quoted opinion is contrary to *Wyeth v. Levine*;

5. Dr. Ehrreich's opinions should additionally be excluded because he has not even read any opinions in the 10 months before his deposition on the subject of whether or not unilateral action can be taken by generic manufacturers can make label changes, accordingly, he has not read this Court's opinion or the opinions of the Eighth or Fifth Circuit Courts of Appeals all of which directly pertain to, contradict and reject the very opinions he seeks, through Mutual counsel, to render at a trial of this case (Ex. ?.

6. Any testimony identifying the statutes, regulations, the congressional record, comments or rulemakings, FDA rules, FDA guidances for the purpose of eliciting testimony to the effect that any or all of them mean, result in or disallow a non-RLD ANDA holder from unilaterally doing CBE label changes to add to, enhance or strengthen safety or risk information in a package insert or label (eg., Dr. Ehrreich's Ex. 1 at pages 15-17 is essentially his legal opinions which are contrary to this Court's opinions and the other cases cited above (exluding Wyeth v. Levine)

7. that no expert be permitted to overcome any hypothetical ruling that they can not provide opinions (as sought to be excluded above) by cloaking such testimony under the veil of what the FDA "wanted", "expected", "desired", "would have approved", "would have considered" or similar description as being either an opinion not covered by any such ruling or that such testimony is purportedly admissible because it is either factually based or a "fact opinion";

8. that no expert be permitted to testify to any opinion not set forth in their reports attached hereto as Exhibits 1A-5A and 1B-2B;

9. the exclusion of Stewart Ehrreich, Ph.D. for Mutual's failure to comply with an agreement to produce his deposition transcripts in his possession seven days prior to his deposition - Exhibits 1A at 8:25-9:22 (Dr. Ehrreich first learned Plaintiff's counsel was entitled to deposition transcripts 7 days in advance of his deposition 2 days before his deposition and Ulmer & Berne still did not comply. Exhibits 6, 7, 8 and 9 demonstrate that there was an agreement and that Ulmer & Berne complied with it for other experts and failed to comply with it for Dr. Ehrreich only. ***Exhibit 13 is a deposition of Dr. Ehrreich on behalf of the Plaintiffs in an NSAID SJS case where he testifies that the label is inadequate for OTC ibuprofen***. Plaintiff was severely prejudiced by not being able to prepare a cross-examination before the deposition with the knowledge of this deposition where he takes many positions which are diametrically opposed to his opinions herein. He should be excluded on this basis alone.

[1] *Foster v. American Home Products Corp.,* 29 F.3d 165, 170 (4th Cir.1994), *Mensing v. Wyeth,* 588 F.3d 603 (8th Cir.2009) and *Demahy v. Actavis, Inc*., 2010 WL 46513 (5th Cir. 2010).

10. Dr. Ehrreich's opinion[2] that Dr. Ergin, Karen Bartlett's prescribing physician, did not specify RLD or generic or which generic company and that Brooks Pharmacy could have filled his prescription with Mylan or Watson (the other two generic makers) or Merck (the maker of the brand name Clinoril/sulindac) instead;

11. Dr. Ehrreich's opinion that the pharmacy likely looked for the most economical version and therefore filled with Mutual's sulindac (Ex. 1 at 3) and that hypothetical that if Brooks pharmacy decided the Mylan version was a better buy and it was hypothetically different continued treatment would not be reasonable (Ex. 1 at 4);

12. Dr. Ehrreich's opinion if Mrs. Bartlett would have received a generic sulindac from Mylan or Watson (the other generic manufacturers) it would have made no difference;

13. that Mrs. Bartlett had "bad luck", "luck of the draw" or other description which characterizes her sulindac-induced TEN or any of its sequalae as a product of uncontrollable or unforeseeable chance (such an opinion seeks a verdict based on sympathy not a scientific opinion or an opinion which can be tested);

14. How many US residents or any other population use NSAIDs at any point in time (Dr. Stern cites the FDA for the proposition that one third of US residents do each year, Ex. 2 at 8) conceding for purposes of this argument that that estimate is correct or low, the opinion is not relevant evokes sympathy because its another way of making a "chance" or "bad luck" argument

15. opinions of Dr. Ehrreich

    a. of what the FDA is "aware of" regarding NSAIDs at any time,
    b. that "[t]he FDA has been aware of the risks posed by NSAIDs for decades" Ex. 1 at 7,
    c. that "the FDA repeatedly has demonstrated its awareness of the risk of SJS with NSAIDs and its ability to review and evaluate that risk" Ex. 1 at 10, and
    d. that "Dr. Salisbury … rightly states that a number of NSAIDS have been withdrawn from the market between 1968 and 2005. Of course FDA is well aware of this and is in a position to either not approve ANDAs for drugs they find unacceptable but actually before that event presents itself to take the parent drug from the market as a definitive step", Ex. 1 at 18;

16. opinions comparing or contrasting the pre-prescription (that is before 12.30.04) labels of other NSAIDs labels to the sulindac pre-prescription label unless those drugs were specifically evaluated by the FDA (allowing such testimony would turn this case into a trial over the risk/benefit profiles of 18 presently marketed NSAIDs instead of one – however if either the FDA specifically assessed a given NSAID or it was taken off

[2] All other topics seeking to exclude or limit Dr. Ehrreich's opinions are sought in case the foregoing request to exclude him is not granted.

the market in either such instance this makes such assessments germane to claims and defenses pertinent to sulindacs risk benefit profile)(ie., Dr. Stern opines regarding his comparative analysis of 10 different NSAID labels and concludes stating "[t]his comparison demonstrates that the 2004 sulindac label was as good or better as any of the NSAID 2004 labels with respect to their warnings concerning severe skin reactions.", Ex. 2 at 6-7 & 17);

17. any expert opine that the Hypersensitivity section of the label in effect when the prescription was made is either a warning for SJS or TEN or that the 2005 label therefore has a redundant or double-warning of SJS/TEN (both in the new mandated section entitled "Skin Reactions" and in the carried over Hypersensitivity section), see Ex. SE 51 at 9.

18. any opinions concerning risks of NSAIDs other than severe skin reactions (ie. GI, GI bleeding and other stomach disturbance, neurologic) unless those were one of the sequalae suffered by Ms. Bartlett. Plaintiffs have never alleged that sulindac should be withdrawn from the market for any different set of risks than SJS/TEN and its complications, allowing such testimony opens up the trial into testimony regarding scores of risks that are not the basis of Plaintiff's claim (Dr. Stern's report page 15 states "Rather, NSAID associated deaths were due to gastrointestinal, renal, other bleeding effects and cardiovascular effects" … quoting an article stating "the most frequent problems are gastrointestinal.")

19. any opinion that class labeling can not be different (no NSAID other than sulindac has a Hypersensitivity section with that information in it, hence, the class labeling in question is different), see, Exs. SE 51 – SE 68 (only two of those labels have a hypersensitivity section in the warning section like sulindac, Exs. SE 51 at 9, SE 54 at 9 and SE 67 at 8).

20. opinions based on the belief, fact, Congressional or legal intent, that generic drugs are less expensive or that generic drug companies would be less profitable, have to raise prices or not be able to stay in business if they also monitored the safety of their drugs, surveyed the medical literature, did dear health care professional letters, did safety studies on their drugs, did changes being effected label changes and/or advocated for any or all of same (eg., Dr. Ehrreich at page 10 opines "[a] generic pharmaceutical company could not provide low cost generic pharmaceuticals as Congress intended if it also had responsibility for such activities for all adverse events for all drugs it sold.")

21. That any act of the conduct described in the foregoing paragraph should not be followed as it would or might burden, heavily burden, bog down or give too much work or place too much responsibility on the FDA (eg., Dr. Ehrreich at page 10 opines "[s]uch actions by generic drug companies would place a heavy burden on the FDA, impair the FDA's ability to conduct its own safety surveillance, and indeed, jeopardize public health and safety.")

22. Dr. Ehrreich's opinion that

    a. "[i]t also is irresponsible to contend that Mutual should have implemented a blackbox warning for sulindac in 2004" given that no such contention was made (Plaintiff contends Mutual should have advocated for one but stipulates that only the FDA can require one), and
    b. "[t]he Tackett report also asserts that generic manufacturers should do "due diligence" studies with regard to **their own product**" Ex. 1 at 15 (em. added) because the Tackett report makes no such assertion. In each instance Dr. Tackett mentions "due diligence" he refers to the due diligence that a potential ANDA holder should do regarding a drug before they initially file their ANDA regarding someone elses product (it can't possibly be your product before you initially file an application for authority to sell a generic version of it). See, Tackett Report, Ex. 10 at 3, 4, 58 & 64. Dr. Tackett had not been deposed when Dr. Ehrreich incorrectly opined so he couldn't have been thinking of deposition testimony.

23. It is not an informative or helpful to a jury to have an opinion claiming another expert is "wrong" or "incorrect" without defining the facts and data upon which the opinion is based, hence, the following "opinions" of Dr. Ehrreich should be excluded:

    a. to the effect that that Dr. Randall Tackett's reports "has so many incorrect statements and misinformation that it is disturbing" that he or anyone else are "shocked and dismayed" (Ex. 1 at 14)
    b. that Dr. Tackett "has no direct knowledge of FDA operations and regulations and has made statements about generic drugs that are unfounded and contrary to regulations" (Ex. 1 at 17) (the two largest topics covered by Dr. Tackett's report are that sulindac caused Karen Bartlett's TEN and sequalae – an opinion shared by defense expert Dr. Stern on a more likely than not basis and by 100% of the treating doctors in this case and that ANDA holders can do CBE label changes to enhance safety information – an opinion supported by this Court and apparently every other court in the country since *Wyeth v. Levine*) and
    c. that any critique of Dr. Tackett's opinions or claims that his opinions are wrong be limited to the four topics which Dr. Ehrreich could identify at his deposition (which was differences of opinion as to CBE label changes to add or enhance safety information, to potentially do safety studies, to potentially advocate to the FDA for label changes and any other conduct which might improve the safety of a generic drug) Ex. 1A at 342:10-345:20.

24. Dr. Ehrreich's opinions to the following effect:

> It is clear that Dr. Tackett who did not spend a single day as an FDA employee, let alone a reviewer or FDA official is not in a position to make assertions about generic drugs that are not true.

Report p. 17 (boldness removed) The opinion is non-sensical. No one is "in a position to make assertions … that are not true" whether they have been with the

FDA or not. In this paragraph Plaintiffs seek to exclude any opinion that a person one is more capable of understanding or interpreting regulations about generic drugs or separately about how generic drug companies should conduct themselves because they spent time at the FDA should be disallowed.

25. Dr. Ehrreichs opinions to the following effect:

> It would be irresponsible of generic drugs companies and contrary to industry standards if generic drugs companies changed the labeling of generic drugs to make the labeling different from the RLD when the FDA has undertaken a campaign to increase confidence in generic drugs by telling the physician and patient public that the labeling for branded and generic drugs is the same.

Report p. 19 (italics removed). It can not be irresponsible to improve the safety of a product by doing something the law permits. The attempt to tether that legally incorrect opinion with an uncited unproduced FDA campaign is an attempted end-run around the likely anticipated motion to exclude such legally invalid opinions. It is also not correct. Class labeling is different and FDA labeling officials have publically opined that generic labels can be different for safety reasons. Ex. 11. Accordingly, opinions to this effect and any testimony referencing such an uncited and unproduced campaign should be disallowed.

26. Dr. Ehrreichs opinions to the following effect:

> The KB adverse event was the first such event reported by MUTUAL… Since this event was the first, there was no history of SJS with MUTUAL's drug **and therefore no new label could have been submitted to FDA for approval**, assuming complete compliance with FDA regulations, that would have warned KB's prescribing physician beforehand.

Ex. 1 at 19 (emphasis added). Plaintiff seeks only to exclude the bold-faced underlined conclusion which is simply a false opinion as labels changes could have been submitted based on medical literature period or based on the 2003 published statement that in an epidemiologic study co-authored by Dr. Stern stating: "[t]he NSAID with the most reports coded as SJS or TEN (sulindac, 89 reports) ranked fifth among all drugs on the basis of total reports." Ex. 12 p. 2237.

27. Dr. Stern's speculative opinions of what is known to any physician, prescribing physician or the medical community about anything, including the risk/benefit profile for any drug and what words like hypersensitivity mean to anyone including him as he does not offer these opinions in his report and hence they should be excluded outright and additionally because he has no evidence to support them. See, Ex. 2A at 127:21-130:5).

28. Dr. Stern's speculative opinions of what is known to any physician, prescribing physician or the medical community about anything, including his opinions that:

> Each patient who uses a medication including most antibiotics, acetaminophen and anti-seizure medications takes a risk that they will develop a severe skin reaction. **This risk is well known to prescribing physicians**"
>
> . . .
>
> Given the widespread use of NSAIDs and the dramatic nature of S[JS] and T[EN], these reports and **the general knowledge in the medical community** that NSAIDs might cause S[JS] and T[EN] **is not surprising**.
>
> **Physicians' and the general medical community's knowledge** that S[JS] and T[EN] are potential NSAID Complications
>
> For more than 20 years, **the general medical community has been aware** that NSAIDs are potential causes of S[JS] and T[EN].
>
> . . .
>
> **The fact that S[JS] and T[EN] are listed in the sulindac label fully informs the prescriber that blindness** and even death are potential rare complication of sulindac use. [because neither the word blind nor blindness appear anywhere in the label it is speculation to conclude that doctors know or are fully informed that SJS/TEN cause blindness]

Ex. 2 at 9, 12 & 16 (emphasis added). Even if Dr. Stern is permitted to testify as to estimates of how many people use NSAIDs he has no basis to opine on what is known, what is the general knowledge of or what is well known to any other doctor or "the medical community".

29. Dr. Stern's attempt to introduce unreliable, unproduced speculation on what is known, what is the general knowledge of or what is well known to any other doctor or the medical community through testimony on how many times his articles or publications have been cited, purchased or how widely distributed or the same information for any other articles or publications. His report states:

> In 1995, we … published the results of the International SJS/TEN study in the *N[EJM]*. This article demonstrated a significant association between oxicam NSAIDs and the risk of S[JS] and T[EN]. This article has been cited more than 500 times. This number of citations indicates the widespread dissemination of the findings of the study including the fact that NSAIDs are potential causes of S[JS] and T[EN].

Ex. 2 at 12-13.

Dated the 19th day of February, 2010.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that this document was filed by the ECF system and served on all counsel of record electronically as a result thereof on the 19th day of February, 2010.

/s/ Keith M. Jensen
Keith M. Jensen